

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Barrett R. Harvey *et al.*

Serial No.: 10/620,278

Filed: July 15, 2003

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Group Art Unit: 1645

Examiner: Ford, V.

Atty. Dkt. No.: UTSB:715US

DECLARATION OF KARL E. GRISWOLD UNDER 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

I, KARL E. GRISWOLD, HEREBY DECLARE AS FOLLOWS:

1. I am a citizen of the United States, and currently reside at 3205-C Grooms Street, Austin, TX, 78705.

2. I have been employed by The University of Texas from 1999 until 2005, with the title of Research Assistant. During that time I was a graduate student at The University of Texas. My primary duties as a Research Assistant were in conducting scientific research in the area of protein engineering. My supervisor was Brent Iverson, Ph.D., who is a co-inventor of the above captioned patent application.

3. I have been conducting research in the area of protein engineering and molecular biology since 1999. I have a Bachelors degree in Chemistry from Southwest Texas State University.

4. I have reviewed the Office Action dated December 20, 2004, the above captioned patent application, the amended claims, and am familiar with the technology and steps described in the amended claims.

5. I understand that the Patent and Trademark Office Examiner in charge of assessing the patentability of the referenced patent application has rejected claim 22 of the application on the grounds that the terms “small molecule” and “synthetic molecule” have no definite meaning.

6. I am therefore providing the present Declaration to demonstrate that those of skill in fields of protein engineering and molecular biology understand the definition of term “small molecule” and “synthetic molecule” as they are used in the specification and claim 22.

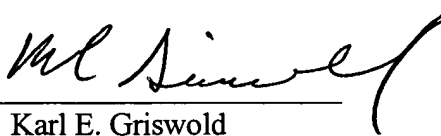
7. The term “small molecule” is in common use in the fields of protein engineering and molecular biology. A researcher of ordinary skill in these fields would understand that the term “small molecule” describes a low molecular weight molecule that is not based on repeating monomeric units. This definition is accepted in the art and well known. For example, a search in PubMed, a database of relevant scientific literature, revealed 788 references in which the words “small molecule” appear in the title alone (Appendix A). This evidences that skilled researchers fully understand the meaning of the term “small molecule.”

8. The term “synthetic molecule” is also common use in the fields of protein engineering and molecular biology. A researcher of ordinary skill in these fields would understand that the term “synthetic molecule” describes a molecule made through the actions of chemicals or biochemicals, as opposed to a molecule that is isolated from the natural world. This definition is accepted in the art and well known. For example, the relevant definition of the term “synthetic” from the online version of the Merriam-Webster online dictionary (<http://www.m-w.com/dictionary.htm>) is given as “produced artificially” (Appendix B). This evidences that meaning of the term “synthetic molecule” is well known to those of skill in the art.

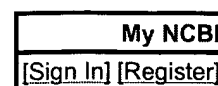
9. Based upon my skill and training in the areas of protein engineering and molecular biology, I therefore conclude that that a researcher of ordinary skill in these fields fully understands the definition of the terms “small molecule” and “synthetic molecule” as they are used in the specification and claims.

10. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

3/4/05
Date


Karl E. Griswold

APPENDIX A



All Databases PubMed Nucleotide Protein Genome Structure OMIM PMC Journals Books

Search PubMed for "small molecule" Go Clear Save Search

☒ Limits Preview/Index History Clipboard Details

Field: Title

About Entrez

Display Summary Show: 20 Sort Send to Text

Text Version

All: 788 Review: 132

Entrez PubMed

Items 1 - 20 of 788

Page 1 of 40 Next

Overview

Help | FAQ

Tutorial

New/Noteworthy

E-Utilities

PubMed Services

Journals Database

MeSH Database

Single Citation Matcher

Batch Citation Matcher

Clinical Queries

LinkOut

My NCBI (Cubby)

Related Resources

Order Documents

NLM Catalog

NLM Gateway

TOXNET

Consumer Health

Clinical Alerts

ClinicalTrials.gov

PubMed Central

☐ 1: [Ray SS, Nowak RJ, Brown RH Jr, Lansbury PT Jr.](#) Related Articles, Links

Small-molecule-mediated stabilization of familial amyotrophic lateral sclerosis-linked superoxide dismutase mutants against unfolding and aggregation.
Proc Natl Acad Sci U S A. 2005 Feb 28; [Epub ahead of print]
PMID: 15738401 [PubMed - as supplied by publisher]

☐ 2: [Selwood T, Smolensky H, McCaslin DR, Schechter NM.](#) Related Articles, Links

The Interaction of Human Trypsin-beta with Small Molecule Inhibitors Provides New Insights into the Unusual Functional Instability and Quaternary Structure of the Protease.
Biochemistry. 2005 Mar 8;44(9):3580-90.
PMID: 15736967 [PubMed - in process]

☐ 3: [Yau CY, Wheeler JJ, Sutton KL, Hedley DW.](#) Related Articles, Links

Inhibition of integrin-linked kinase by a selective small molecule inhibitor, QLT0254, inhibits the PI3K/PKB/mTOR, Stat3, and FKHR pathways and tumor growth, and enhances gemcitabine-induced apoptosis in human orthotopic primary pancreatic cancer xenografts.
Cancer Res. 2005 Feb 15;65(4):1497-504.
PMID: 15735038 [PubMed - in process]

☐ 4: [Buskirk AR, Liu DR.](#) Related Articles, Links

Creating small-molecule-dependent switches to modulate biological functions.
Chem Biol. 2005 Feb;12(2):151-61.
PMID: 15734643 [PubMed - in process]

☐ 5: [Berkson RG, Hollick JJ, Westwood NJ, Woods JA, Lane DP, Lain S.](#) Related Articles, Links

Pilot screening programme for small molecule activators of p53.
Int J Cancer. 2005 Feb 23; [Epub ahead of print]
PMID: 15729694 [PubMed - as supplied by publisher]

☐ 6: [Toenjes KA, Munsee SM, Ibrahim AS, Jeffrey R, Edwards JE Jr, Johnson DL.](#) Related Articles, Links

Small-Molecule Inhibitors of the Budded-to-Hyphal-Form Transition in the Pathogenic Yeast *Candida albicans*.
Antimicrob Agents Chemother. 2005 Mar;49(3):963-72.
PMID: 15728890 [PubMed - in process]

☐ 7: [Liu J, Wu X, Mitchell B, Kintner C, Ding S, Schultz PG.](#) Related Articles, Links

APPENDIX B



Merriam-Webster Online

Merriam-Webster FOR KIDS

Encyclopædia BRITANNICA

Merriam-Webster ONLINE

Merriam-Webster COLLEGIATE®

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WORD GAMES

WORD FOR THE WISE

ONLINE STORE

HELP

Merriam-Webster Inc.
Company Information

Merriam-Webster Online Dictionary

5 entries found for **synthetic**.
To select an entry, click on it.

synthetic[1,adjective]
synthetic[2,noun]
synthetic division
synthetic geometry
synthetic resin



Thesaurus

Merriam-Webster Online

- ◉ Dictionary
- ◉ Thesaurus



synthetic



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Main Entry: **¹syn-thet-ic**
Pronunciation: sin-'the-tik

Function: *adjective*

Etymology: Greek *synthetikos* of composition, component,
from *synthithenai* to put together

1 : relating to or involving synthesis : not analytic
2 : attributing to a subject something determined by
observation rather than analysis of the nature of the subject
and not resulting in self-contradiction if negated -- compare
ANALYTIC

3 : characterized by frequent and systematic use of inflected
forms to express grammatical relationships

4 a (1) : of, relating to, or produced by chemical or
biochemical synthesis; *especially* : produced artificially
<*synthetic* drugs> <*synthetic* silk> **(2)** : of or relating to a
synfuel **b** : devised, arranged, or fabricated for special
situations to imitate or replace usual realities **c** :

FACTITIOUS, BOGUS

- **syn-thet-i-cal-ly** /-ti-k(&-)lE/ *adverb*

For More Information on "synthetic" go to [Britannica.com](#)

Get the Top 10 Search Results for "synthetic"